

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Civ. Action No. 8:18-cv-883-PWG

PLAINTIFFS' PROPOSED REMEDIAL ORDER

Upon consideration of the May 15, 2019 Order vacating, the August 2017 Guidance issued by the U.S. Food and Drug Administration (“FDA”), for the reasons stated in the Court’s May 15, 2019 Memorandum Opinion; the parties’ submissions with respect to the appropriate remedy; and to ensure FDA’s compliance with the mandatory premarket review process in the Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”), Pub. L. No. 111-31, 123 Stat. 1776 (2009), and remedy the harm to public health caused by the August 2017 Guidance, it is this ____ day of ____ hereby ORDERED that:

1. FDA will take any and all actions necessary, and in accord with the Administrative Procedure Act, to ensure that no new tobacco product (as that term is defined in Section 910(a)(1) of the Tobacco Control Act, 21 U.S.C. § 387j(a)(1)) subjected to FDA regulation pursuant to the Deeming Rule, 81 Fed. Reg. 28,974 (May 10, 2016), and on the market as of August 8, 2016 (the effective date of the Deeming Rule) may remain on the market without being subject to FDA enforcement action unless an application for a Marketing Order for such product is received by FDA within 120 days of the date of this Remedial Order. For

purposes of this Order, an application shall be deemed to have been filed on the date it is received by FDA.

2. New tobacco products for which applications have been timely filed may remain on the market without being subject to FDA enforcement action for a period not to exceed one year from the date an application is received by FDA or until such application has been denied, whichever event (the lapse of the one-year period or a denial) occurs first, unless such application has been granted within the one-year period.

3. Nothing in this Order shall bar FDA from establishing, for certain new tobacco products or categories of new tobacco products, a shorter period of time, including no period of time, than that established pursuant to paragraphs 1 and 2 of this Order, during which they may remain on the market without a Marketing Order without being subject to FDA enforcement action.

4. FDA shall file a report with the Court and Plaintiffs every 90 days, beginning on _____, describing (1) all steps it is taking to discharge its statutory duty to subject new tobacco products to premarket review, (2) the number and nature of the enforcement actions it has commenced against companies for marketing their products without a Marketing Order, and (3) the number of applications for Marketing Orders it has received and the status of its processing of those applications.

5. For purposes of this Order, the term Marketing Order means (1) an FDA Order granting premarket authorization for the marketing of a new tobacco product pursuant to Section 910 of the Tobacco Control Act; (2) an FDA Order granting an application for Substantial Equivalence pursuant to Sections 905(j) and 910 of the Tobacco Control Act; or (3) an FDA

Order finding a new tobacco product is exempt from demonstrating Substantial Equivalence pursuant to Section 910(j)(3) of the Tobacco Control Act.

The Court shall retain jurisdiction over this matter for the purpose of enforcing the May 15, 2019 Summary Judgment Opinion and Order as well as this Order.

SO ORDERED.

Paul W. Grimm
United States District Judge